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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAND, MELANIE JO	
ART UNIT	**PAPER NUMBER**
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/090,358	TUMEY, DAVID	
	Examiner	Art Unit	
	MELANIE J. HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10 and 21-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-10 and 21-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/09,7/15/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's arguments traversing the election of species requirement are persuasive. Therefore the requirement is withdrawn.

Response to Arguments

2. Applicant's arguments with respect to claims 1 and 5-10 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims.

3. The rejection of claims 19 and 20 under 35 U.S.C. 112 made in the final action is moot in view of the amendment to the claims cancelling claims 19 and 20.

Information Disclosure Statements

4. The information disclosure statements (IDS) submitted on January 26, 2009 and July 15, 2009 were filed after the mailing date of the final action on October 24, 2008. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for the phrase "in optical proximity" recited in independent claim 1 as amended and newly presented independent claim 27.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 5 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As the phrase “in optical proximity" doe snto appear anywhere in the specification, there is no clear and explicit definition for the phrase, rendering independent claims 1 and 27 indefinite, as well as the claims dependent therefrom.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 5, 6, 10, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (WO 00/59424 A1) in view of Overton et al (U.S. Patent No. 5,611,846).

With respect to **claim 1:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a gas chromatograph operable to sense compositional characteristics of unfiltered wound fluid from the wound bed interposed between said screen

means 11 and said vacuum source. Johnson also does not disclose or suggest a gas chromatograph that further comprises a photodiode operable in optical proximity to fluids being drawn from the wound bed toward said vacuum source, wherein the gas chromatograph detects a light frequency as the fluids pass the photodiode. Overton discloses a gas chromatograph (GC) that is a chromatograph disclosed by applicant for use with the claimed device and is thus necessarily operable to sense compositional characteristics of unfiltered wound fluid from the wound bed. The GC necessarily further comprises a photo diode inasmuch as Overton discloses that a photoionization detector (PID) 212 is electrically connected to the column to detect a change in conductivity. A photo diode is given its common meaning in the interpretation of claim 1, i.e. a photodetector capable of turning light into current or voltage. (‘846, Col. 12, lines 20-28) The photodiode in the form of PID 212 is operable in optical proximity to fluids being passed through column 210. The GC with PID 212 therein detects a light frequency, specifically UV light from source 222 associated with a change in conductivity as a result of passing the light through the gas stream. Overton discloses a computer processing unit in the form of a data processing module that necessarily stores light frequencies or changes therein because Overton discloses comparisons to different columns from the same device which employs a photodetector to determine the identity of analytes. Thus Overton discloses a computer processing unit comprising a database that stores light frequencies associated with microorganisms, i.e. the analytes. The device of Overton also comprises a software program operable to compare the light frequency detected by the GC with light frequencies stored in the database to identify the analytes. ('846, Col. 3, lines 41-53) Overton discloses that this GC is portable and operates at high speed with minimal consumption of utilities. (‘846, Abstract) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to comprise a gas chromatograph, computer processing unit and software program as

disclosed by Overton to allow identification of analytes in unfiltered wound fluid to determine the physiological status of the wound bed environment for diagnostic purposes. The GC of the device of Johnson as modified by Overton would thus comprise a photo diode operable in optical proximity to fluids being drawn from the wound bed through the GC column toward the vacuum source, wherein the GC detects a light frequency (specifically, UV light) as the fluids pass the photodiode.

With respect to **claim 6:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14 (flexible conduit for communicating between screen means and vacuum source). Johnson teaches a collection canister interposed between said screen means and said vacuum source. (Page 4, lines 18-21)

Johnson does not teach a sensor array operable to sense compositional characteristics of unfiltered wound fluid from the wound bed interposed between said screen means 11 and said vacuum source. Overton discloses a sensor array in the form of a GC having a combined photoionization detector/flame ionization detector wherein the detectors are in series, defining a sensor array. The chromatograph disclosed by Overton is disclosed by applicant as a GC for use with the claimed device and thus the array is necessarily operable to sense compositional characteristics of unfiltered wound fluid from the wound bed. Overton discloses that this GC is portable and operates at high speed with minimal consumption of utilities. (‘846, Abstract)

Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to comprise a gas chromatograph, computer processing unit and software program as disclosed by Overton to allow identification of analytes in unfiltered wound fluid to determine the physiological status of the wound bed environment for diagnostic purposes. The GC of the device of Johnson as modified by Overton would thus comprise a photo diode operable in optical proximity to fluids being drawn from the wound bed through the GC column toward the vacuum source, wherein the GC detects a light frequency (specifically, UV light) as the fluids pass the photodiode. Thus, the compositional characteristics detected by the GC of Overton when used with the device of Johnson are necessarily indicative of infection as the presence of any bacterium would be detected by the GC via said data processing module. If the fluid passing through the column of the GC is wound exudate as would be the case, the compositional characteristics necessarily include a presence of a bacterium. The sensor array would also necessarily comprise regions of conducting nonorganic material (i.e the compressed gas in the gas stream) and regions of conducting organic material, i.e. wound exudate, compositionally different than the nonconducting organic material.

With respect to **claim 10:** The negative pressure therapy device of Johnson further comprises a flexible conduit in the form of material hose 14 for communicating between said screen means 11 and said vacuum source.

With respect to **claim 21:** The microorganisms disclosed by Johnsons in the wound exudate necessarily include an antigen. Examiner’s position is based upon Johnson's disclosure of modification of the screen means 11 for introduction of a growth factor which would not be

necessary or perform its intended function if an antigen were not present. (‘240, Col. 3, lines 59-64)

With respect to **claim 22:** The negative pressure therapy device of Johnson as modified by Overton further comprises a display in the form of a chromatogram operable to transmit visual notification if the software program identifies a match between the light frequency detected by the gas chromatograph and at least one of the light frequencies stored in the database, inasmuch as the chromatogram identifies the substance by a code, e.g. C17 (see Figs. 9 and 10), which can only be obtained subsequent to matching the detector results with previously stored chromatograms.

10. Claims 7, 23, 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson (‘424) in view of Overton et al (‘846), as applied to claims 1 and 6 above, and in further view of Scherson et al. ('570).

With respect to **Claims 7,24:** Johnson does not teach a sensor array embedded in the screen means 11. Overton discloses a sensor array but does not disclose a location in the screen means within a wound bed. Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. It would be obvious to one with ordinary skill in the art to embed the sensor array of the device of Overton in the screen means of Johnson in the manner disclosed by Scherson to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site.

With respect to **claim 23:** The negative pressure therapy device of Johnson further comprises a filtration mechanism in the form of a hydrophobic filter. Johnson does not disclose a gas chromatograph interposed between the wound bed and the filtration mechanism. Overton discloses a GC but does not disclose any position relative to a wound bed. Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. It would be obvious to one with ordinary skill in the art to embed the sensor array of the device of Overton in the screen means of Johnson in the manner disclosed by Scherson to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site. A GC embedded within the screen means of the device of Johnson as modified by Overton would thus be interposed between the wound bed and the filtration mechanism since Johnson discloses that the filter is interposed between the vacuum pump and a collection canister. ('240, Col. 3, lines 46-51)

With respect to **claim 27:** Johnson teaches a negative pressure therapy device, comprising a screen means in the form of a highly reticulated open-cell foam pad 11 for placement within a wound bed 12 (Page 3, lines 32-34, Page 4, lines 14-16), a sealing means in the form of wound drape 13 adhered over said screen means 11 and wound bed 12 (Page 3, lines 32-34) via at least peripheral coverage of the drape 13 with adhesive (Page 4, lines 21-23), and a vacuum source fluidically communicating with said screen means 11 via material hose 14.

Johnson does not teach a gas chromatograph operable to sense compositional characteristics of unfiltered wound fluid from the wound bed interposed between said screen means 11 and said vacuum source. Johnson also does not disclose or suggest a gas chromatograph that further comprises a photodiode operable in optical proximity to fluids being

drawn from the wound bed toward said vacuum source, wherein the gas chromatograph detects a light frequency as the fluids pass the photodiode. Overton discloses a gas chromatograph (GC) that is a chromatograph disclosed by applicant for use with the claimed device and is thus necessarily operable to sense compositional characteristics of unfiltered wound fluid from the wound bed. The GC necessarily further comprises a photo diode inasmuch as Overton discloses that a photoionization detector (PID) 212 is electrically connected to the column to detect a change in conductivity. A photo diode is given its common meaning in the interpretation of claim 1, i.e. a photodetector capable of turning light into current or voltage. (‘846, Col. 12, lines 20-28) The photodiode in the form of PID 212 is operable in optical proximity to fluids being passed through column 210. The GC with PID 212 therein detects a light frequency, specifically UV light from source 222 associated with a change in conductivity as a result of passing the light through the gas stream. Overton discloses a computer processing unit in the form of a data processing module that necessarily stores light frequencies or changes therein because Overton discloses comparisons to different columns from the same device which employs a photodetector to determine the identity of analytes. Thus Overton discloses a computer processing unit comprising a database that stores light frequencies associated with microorganisms, i.e. the analytes. The device of Overton also comprises a software program operable to compare the light frequency detected by the GC with light frequencies stored in the database to identify the analytes. ('846, Col. 3, lines 41-53) Overton discloses that this GC is portable and operates at high speed with minimal consumption of utilities. (‘846, Abstract) Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Johnson so as to comprise a gas chromatograph, computer processing unit and software program as disclosed by Overton to allow identification of analytes in unfiltered wound fluid to determine the physiological status of the wound bed environment for diagnostic purposes. The GC of the

device of Johnson as modified by Overton would thus comprise a photo diode operable in optical proximity to fluids being drawn from the wound bed through the GC column toward the vacuum source, wherein the GC detects a light frequency (specifically, UV light) as the fluids pass the photodiode.

As to the limitation regarding a display, the negative pressure therapy device of Johnson as modified by Overton further comprises a display in the form of a chromatogram operable to transmit visual notification if the software program identifies a match between the light frequency detected by the gas chromatograph and at least one of the light frequencies stored in the database, inasmuch as the chromatogram identifies the substance by a code, e.g. C17 (see Figs. 9 and 10), which can only be obtained subsequent to matching the detector results with previously stored chromatograms.

The negative pressure therapy device of Johnson further comprises a filtration mechanism in the form of a hydrophobic filter. Johnson does not disclose a gas chromatograph interposed between the wound bed and the filtration mechanism. Overton discloses a GC but does not disclose any position relative to a wound bed. Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. It would be obvious to one with ordinary skill in the art to embed the sensor array of the device of Overton in the screen means of Johnson in the manner disclosed by Scherson to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site. A GC embedded within the screen means of the device of Johnson as modified by Overton would thus be interposed between the wound bed and the filtration mechanism since Johnson discloses that the filter is interposed between the vacuum pump and a collection canister. (‘240, Col. 3, lines 46-51)

With respect to **Claim 28:** Johnson does not teach a sensor array embedded in the foam pad 11. Overton discloses a sensor array but does not disclose a location in the screen means within a wound bed. Scherson teaches an oxygen-producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. It would be obvious to one with ordinary skill in the art to embed the sensor array of the device of Overton in the foam pad of Johnson in the manner disclosed by Scherson to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site.

11. Claims 8 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Overton et al ('846) as applied to claims 6 and 27 above, and further in view of Fleischmann (U.S. Patent No. 6,398,767).

With respect to **Claims 8,25:** The device of Johnson as modified by Overton contains a sensor array and a sealing means but neither Johnson nor Overton discloses or suggests a sensor array disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 ('767, Fig. 1 and Col. 4, lines 62-64). Since the device of Fleischmann seeks to solve a similar problem in the art to that with which applicant is concerned, it would be obvious to one with ordinary skill in the art to modify the sensor array and sealing means taught by the combined teaching of Johnson and Overton such that the sensor is disposed on the sealing means to detect infections in the atmosphere near the wound area as taught by Fleischmann.

12. Claims 9 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson ('424) in view of Overton et al ('846), as applied to claim 6 above, and further in view of Parker et al (U.S. Patent No. 4,955,391).

With respect to **Claims 9,26:** The device of Johnson as modified by Overton contains a sensor array and a sealing means but neither Johnson nor Overton discloses or suggests a sensor array disposed within the collection canister. Parker teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col.5, lines 16-21) to monitor parameters of the fluid collected. This provides additional and more accurate means for detecting infection at the wound site as taught by Parker. Therefore, it would be obvious to one with ordinary skill in the art to provide the invention of the combined teaching of Johnson and Overton with the sensing probe of Parker inside of the instant collection canister to provide additional and more accurate means for detecting infection at the wound site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761